K072362

OCT 23 2007

510(k) Summary
for the Novalung® GmbH
Novalung® surgical Lung Assist (sLA) Membrane Lung™

1. SUBMITTER/510(K) HOLDER

Novalung® GmbH
Lotzenäcker 3
D-72379 Hechingen, Germany

Contact Person: Heiko Frerichs
Telephone: +49 7471 98488-30

Date Prepared: August 21, 2007

2. DEVICE NAME

Proprietary Name:	Novalung® surgical Lung Assist (sLA) Membrane Lung™
Common/Usual Name:	Cardiopulmonary bypass oxygenator
Classification Name:	Oxygenator, cardiopulmonary bypass

3. PREDICATE DEVICES

- Jostra Quadrox D Safeline Diffusion Membrane Oxygenator (Maquet Cardiovascular AG, K061628)

4. DEVICE DESCRIPTION

The Novalung® surgical Lung Assist (sLA) Membrane Lung™ is a sterile device for single use only and it is not intended to be resterilized by the user. The Novalung® surgical Lung Assist (sLA) Membrane Lung™ is used to deliver oxygen into the blood and remove carbon dioxide from the blood. It is intended to be used as a component in an extracorporeal circuit for patients undergoing cardiopulmonary bypass. The Novalung® surgical Lung Assist (sLA) Membrane Lung™ incorporates a solid surface hollow polymethylpentene (PMP) fiber membrane and has a 1.3 m^2 surface area. The Novalung® surgical Lung Assist (sLA) Membrane Lung™ has a nominal flow range from 0.5 L/min. to 4.5 L/min and is suitable for patients weighing ≥20kg.

5. INTENDED USE

The Novalung® surgical Lung Assist (sLA) Membrane Lung™ is intended to be used for extracorporeal circulation during cardiopulmonary bypass in the field of open-heart surgery. Within the indicated flow rates, blood is oxygenated and carbon dioxide is removed. The utilization period of this device is restricted to six hours:

The application and use of the oxygenator is the sole responsibility of the attending physician.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Novalung® surgical Lung Assist (sLA) Membrane Lung™ has the same intended use, design, principals of operation, and performance as the Jostra Quadrox D Safeline Diffusion Membrane Oxygenator. The Jostra Quadrox D Safeline Diffusion Membrane Oxygenator uses a tight diffusive membrane, where as the Novalung® surgical Lung Assist (sLA) Membrane Lung™ uses a solid surface membrane. The Quadrox D offers 1.8 m^2 surface area and a blood flow range of 0.5 L/min to 7 L/min. The Novalung® surgical Lung Assist (sLA) Membrane Lung™ provides the user with a smaller surface area of 1.3m^2 and a reduced flow range of 0 L/min to 4.5 L/min. Comparative testing has demonstrated that these differences do not raise new issues of safety and effectiveness.

7. PERFORMANCE TESTING

The Novalung® surgical Lung Assist (sLA) Membrane Lung™ has been fully characterized by bench testing in accordance with FDA Guidance. A failure mode and effects analysis has been performed to identify potential failure modes of the device. Potential failure modes directly related to the design and function of the Novalung® surgical Lung Assist (sLA) Membrane Lung™ have been evaluated in vitro and results are provided in the premarket notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2007

Novalung® GmbH
c/o Mr. Heiko Frerichs
Lotzenäcker 3
D-72379 Hechingen, Germany

Re: K072362
Novalung® Surgical Lung Assist (sLA) Membrane Lung™
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: August 21, 2007
Received: August 22, 2007

Dear Mr. Frerichs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072362

Device Name: Novalung® surgical Lung Assist (sLA) Membrane Lung™

Indications for Use:

The Novalung® surgical Lung Assist (sLA) Membrane Lung™ is intended to be used for extracorporeal circulation during cardiopulmonary bypass in the field of open-heart surgery. Within the indicated flow rates blood is oxygenated and carbon dioxide is removed. The utilization period of this device is restricted to six hours.

Prescription Use X AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072362